



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Anil Taneja
Chief Executive Officer
PT. Medisafe Technologies
JL. Batang Kuis GG. Tambak Rejo
Desa Buntu Bedimbar TJ. Morawa
Medan, North Sumatera
Indonesia 20362

JUN - 6 2011

Re: K102623

Trade/Device Name: Powder-Free Blue Nitrile Examination Gloves Tested for Use
with Chemotherapy Drugs

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Gloves

Regulatory Class: I

Product Code: LZA, LZC

Dated: May 16, 2011

Received: May 23, 2011

Dear Mr. Taneje:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

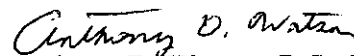
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

ATTACHMENT B

Indications for Use

Applicant : Medisafe Technologies

510(k) Number (if known): Not Known

Device Name: Powder-Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs.

Indications For Use:

Powder-Free Blue Nitrile Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between Examiner and Patient. Tested for use with Chemotherapy Drugs as listed below.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes.		
The following chemicals have been tested with these gloves		
1	Carmustine	1.04
2	Cisplatin	>240
3	Cyclophosphamide	>240
4	Dacarbazine	>240
5	Doxorubicin Hydrochloride	>240
6	Etoposide	>240
7	Flourouracil	>240
8	Paclitaxel	>240
9	Thiotepa	= 165

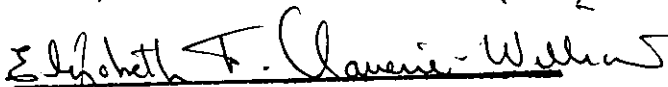
Please note that Carmustine has an extremely low permeation time of less than 30 minutes.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒ _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102623